Initial Approval Date: July 10, 2019
Revised Dates: April 21, 2021; July 8, 2020;
October 9, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Ulcerative Colitis Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Adalimumab (Humira®, Amjevita™, Cyltezo®™, Hyrimoz™, Hadlima™, Abrilada™)
Golimumab (Simponi®)
Infliximab (Remicade®, Renflexis®™, Inflectra®, Ixifi™, Avsola™)
Tofacitinib (Xeljanz®, Xeljanz® XR)
Ustekinumab (Stelara®)
Vedolizumab (Entyvio®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a gastroenterologist.
- For induction of remission: Patient must meet ONE of the following as determined by the provider:
  - Had an adequate trial (at least 4 weeks)[3] of an oral systemic corticosteroid equivalent to 40-60 mg/day prednisone with a planned dose taper.[2,3,5]
  - Had an inadequate response within 3-5 days of an intravenous corticosteroid (IVCS) equivalent to 60 mg/day methylprednisolone or 100 mg hydrocortisone 3-4 times per day for the induction of remission.[2]
- For maintenance of remission: Patient must fail to achieve mucosal healing within 4 months[4] or have had a relapse at any time despite continuous use of any conventional therapy listed in Table 2. Mucosal healing is defined as ONE of the following:[2]
  - Endoscopic evidence of mucosal healing defined as Mayo subscore ≤ 1.[2]
  - Fecal Calprotectin ≤ 150 µg/g.[2]
- For tofacitinib, patient must have had an adequate trial (at least 6-8 weeks)[6-15,18] of or contraindication to a Tumor Necrosis Factor (TNF) blocker listed in Table 1. [16,21]
- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide baseline of at least ONE of the following assessments of moderate to severe disease:[1,2]
  - Fecal calprotectin (FC) > 150 µg/g[2]
  - Endoscopy Mayo subscore ≥ 2[1,2]
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Ulcerative Colitis (UC) Agents.[6-19,22]

Medication	Indication(s)	Age	Dosing Limits
Interleukin-12 and -23 Inhibitors			
Ustekinumab (Stelara®)	UC	≥ 18 years	Initial IV Dose: ≤ 55 kg: 260 mg as a single dose. >55-85 kg: 390 mg as a single dose. >85 kg: 520 mg as a single dose. SC: 90 mg every 8 weeks beginning 8 weeks after the IV induction dose.
Janus Associated Kinase Inhibitors			
Tofacitinib (Xeljanz®, Xeljanz® XR)	UC, in those with an inadequate response or intolerance to TNF blockers	≥ 18 years	Immediate release: 10 mg orally twice daily for 8 weeks then 5 or 10 mg twice daily Extended release: 22 mg once daily for 8 weeks then 11 or 22 mg once daily
Selective Adhesion-Molecule Inhibitor			
Vedolizumab (Entyvio®)	UC	≥ 18 years	300 mg IV at 0, 2, and 6 weeks, and then every 8 weeks thereafter.
Tumor Necrosis Factor-Alpha (TNF-α) Blockers			
Adalimumab (Humira®~~), Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™, Abrilada™)~~	UC	≥ 5~~18~~ years	**Adults ≥ 18 years:** 160 mg initially SC on day 1 (given as a single dose~~on day 1~~ or split and given over 2 consecutive days), followed by 80 mg 2 weeks later (day 15) and then 40 mg every other week beginning 2 weeks later (day 29). **≥ 5 years to < 18 years:** 20 kg to < 40 kg: 80 mg SC on day 1, followed by 40 mg on days 8 and 15 and then 40 mg every other week or 20 mg every week beginning on day 29. ≥ 40 kg: 160 mg SC on day 1 (given as a single dose or split over 2 consecutive days), followed by 80 mg on days 8 and 15 and then 80 mg every other week or 40 mg every week beginning on day 29.
Adalimumab (Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, Abrilada™)	UC	≥ 18 years	Adults ≥ 18 years: 160 mg initially SC on day 1 (given as a single dose or split and given over 2 consecutive days), followed by 80 mg 2 weeks later (day 15) and then 40 mg every other week beginning 2 weeks later (day 29).
Golimumab (Simponi®)	UC	≥ 18 years	200 mg initially SC at week 0, followed by 100 mg at week 2 and then 100 mg every 4 weeks.
Infliximab (Remicade®, Renflexis®™, Inflectra®, Ixifi™, Avsola™)	UC	≥ 6 years	5 mg/kg at IV 0, 2, and 6 weeks, then every 8 weeks.

SC: subcutaneous. IV: intravenous

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Prescriber must provide at least ONE of the following response measure(s):
  - Endoscopic evidence of mucosal healing defined as ONE of the following:
    - Mayo subscore ≤ 1.[1,2]
    - Fecal Calprotectin ≤ 150 µg/g.[2]
- Must not exceed dosing limits listed in Table 1.
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of UC[1,4]

Conventional Agents for Maintenance of Remission of Moderate to Severe UC	
Generic Name	**Brand Name**
Azathioprine	Azasan®, Imuran®
Mercaptopurine	Purinethol®

Table 3. List of immunomodulating biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Immunomodulating Biologic Agents/Janus Kinase Inhibitors		
Abrilada™ (adalimumab-afzb)	Humira® (adalimumab)	Rituxan Hycela™ (rituximab/hyaluronidase)
Actemra® (tocilizumab)	Hyrimoz™ (adalimumab-adaz)	Ruxience™ (rituximab-pvvr)
Amevive® (alefacept)	Ilaris® (canakinumab)	Siliq® (brodalumab)
Amjevita™ (adalimumab-atto)	Ilumya™ (tildrakizumab-asmn)	Simponi® (golimumab)
Avsola™ (infliximab-axxq)	Inflectra® (infliximab-dyyb)	Simponi Aria (golimumab)
Cimzia® (certolizumab)	Ixifi™ (infliximab-qbtx)	Skyrizi™ (Risankizumab-rzaa)
Cinqair® (reslizumab)	Kevzara® (sarilumab)	Stelara® (ustekinumab)
Cosentyx® (secukinumab)	Kineret® (anakinra)	Taltz® (ixekizumab)
Cyltezo®™ (adalimumab-adbm)	Nucala® (mepolizumab)	Tremfya® (guselkumab)
Dupixent® (benralizumab)	Olumiant® (baricitinib)	Truxima® (rituximab-abbs)
Enbrel® (etanercept)	Orencia® (abatacept)	Tysabri® (natalizumab)
Entyvio® (vedolizumab)	Remicade® (infliximab)	Xeljanz® (tofacitinib)
Erelzi™ (etanercept-szzs)	Renflexis® (infliximab-abda)	Xeljanz XR® (tofacitinib)
Eticovo® (etanercept-ykro)	Riabni™ (rituximab-arrx)	Xolair® (omalizumab)

Fasenra™ (benralizumab)	Rinvoq™ (upadacitinib)	
Hadlima™ (adalimumab-bwwd)	Rituxan® (rituximab)	

Table 4. Relative Potencies for Oral/Intravenous Corticosteroids.[20]

Glucocorticoid	Relative Potency
Short-Acting	
Cortisone	25
Hydrocortisone	20
Intermediate-Acting	
Prednisone	5
Prednisolone	5
Methylprednisolone	4
Long-Acting	
Dexamethasone	0.75

Table 4 is intended for reference only.

Notes:

Adalimumab	Only continue adalimumab in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.
Golimumab	Simponi Aria is not indicated for ulcerative colitis (UC).
Tofacitinib	Use of tofacitinib in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Discontinue tofacitinib after 16 weeks, if adequate therapeutic benefit is not achieved. In July 2019, the FDA ~~has~~ issued a safety alert warning about an increased risk of blood clots and death with the 10 mg twice-daily dose of tofacitinib, which is used in patients with ulcerative colitis. The approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines.[21] In February 2021, the FDA issued a safety communication alerting that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with tofacitinib compared to other TNF inhibitors.[23]
Vedolizumab	Discontinue vedolizumab in patients who show no evidence of therapeutic benefit by week 14.

References:

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3. Glucocorticosteroid Therapy in Inflammatory Bowel Disease: Systematic Review and Meta-Analysis. Am J of Gastroenterol 2011; 106(4): 590-9. Available at https://insights.ovid.com/pubmed?pmid=21407179. Accessed on 6/15/20.

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7. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; ~~March 2018~~June 2019.
8. Cyltezo (adalimumab- adbm) [prescribing information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals Inc: ~~August 2017~~September 2019.
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12. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; ~~June 2019~~August 2020.
13. Renflexis (infliximab-abda) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; ~~June~~ October 2019.
14. Ixifi (infliximab-qbtx) [prescribing information]. Ringaskiddy, Co. Cork, Ireland: Pfizer Ireland Pharmaceuticals; January 2020.
15. Avsola (infliximab-axxq) [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2019.
16. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer~~; December 2019~~; October 2020.
17. Entyvio (vedolizumab) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America Inc; ~~May 2019~~March 2020.
18. Hadlima (adalimumab-bwwd) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; July 2019.
19. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc; ~~November 2019~~December 2020.
20. Solu-Medrol (methylprednisolone sodium succinate) [prescribing information]. New York, NY: Pfizer; July 2018.
21. U.S. Food and Drug Administration. FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR), July 26, 2019. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and. Accessed on 3/16/20.
22. Hyrimoz (adalimumab-adaz) [prescribing information]. Princeton, NJ: Sandoz, Inc; October 2018.
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